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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-81

September 4, 1997

Rafael Lapon, President
Progressive Medical Services
7545 West 24th Avenue
Hialeah, Florida 33016

Dear Mr. Lapon:

Inspection of your medical gas filling operation on August 14-18, 1997, by FDA investigator Jennifer M. Donzanti, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (GMP) Regulations for drugs [Title 21, Code of Federal Regulation, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you have failed to test each component lot of bulk compressed oxygen to determine conformance with appropriate specifications prior to use, or in lieu of testing, receive a valid certificate of analysis from your supplier and conduct an identity test. Refilled cylinders of compressed medical Oxygen USP are not tested for purity and identity prior to release for distribution. In addition, the [redacted] Oxygen Analyzer used by your firm is not an acceptable test device for oxygen purity in that the device is not equivalent to the USP test accuracy of ± 0.1%

Batch production and control records are not maintained documenting that each significant step in the manufacturing operation was completed, such as all required pre and post fill cylinder inspections and testing. Records documenting calibration and maintenance of equipment are not maintained, and no system is established to assign unique lot numbers to cylinders from each uninterrupted filling sequence. No written procedures are established for handling of complaints, and there is no assurance that you have received adequate training in drug GMP's.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the GMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of the GMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District